

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 67595-72137	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/SE2003/001132	International filing date (day/month/year) 27.06.2003	Priority date (day/month/year) 03.07.2002
International Patent Classification (IPC) or national classification and IPC A41D 13/12, A41D 13/005, A61F 7/00, A61B 19/08		
Applicant Mölnlycke Health Care AB et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
- a. ☒ (sent to the applicant and to the International Bureau) a total of 2 sheets, as follows:
- ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
- ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
- b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:
- | | | |
|-------------------------------------|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

Date of submission of the demand 20.01.2004	Date of completion of this report 30.09.2004
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88	Authorized officer Anette Eriksson / MRO Telephone No. +46 8 782 25 00

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))
☐ publication of the international application (under Rule 12.4)
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:

pages 1 - 8 as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ the claims:

pages _____ as originally filed/furnished

pages* _____ as amended (together with any statement) under Article 19

pages* 1 - 2 received by this Authority on 07.07.2004

pages* _____ received by this Authority on _____

☒ the drawings:

pages 1 as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	<u>1-10</u>	YES
	Claims		NO
Inventive step (IS)	Claims	<u>1-10</u>	YES
	Claims		NO
Industrial applicability (IA)	Claims	<u>1-10</u>	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)**INVENTION**

The invention relates to a patient garment having sleeves and comprising a front and a back piece. Objects of the invention are to produce a warming garment for a patient, which can be used before, during and after a surgical operation and which covers the patient during movement of the patient between the wards and the operating theatre. This is achieved by the garment having sleeves and comprising a front and a back where the front piece is made up of an outer layer of a material of little air permeability and an inner layer of a material with a significantly higher air permeability than the outer layer. The inner and outer layers are attached to each other and a space is formed between them. An inlet connectable to a source of warm air is located on the front piece and leads to the space between the layers. Warm air is supplied to the patient's skin.

CITED DOCUMENTS

D1: US6012179A
D2: US5735890A
D3: US5405370A
D4: US3738367A
D5: US5383918A

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX V

DISCUSSION AND CONCLUSION

Claims 1-10

D1 discloses a garment for use by a patient during an operation. An object of the invention is to control the body temperature of the patient. The garment covers the body and limbs of the patient. Preferably the garment includes at least one space or opening to allow access to the patient where the operation is to be performed. The garment includes an inner skin (8) and an outer skin (10). A space (12) is formed between the skins (8, 10) and it forms a part of a circuit for a gas mixture of air and helium to control the body temperature of the patient. An inlet (16) and an outlet (18) are attached to the space (12). The garment cools the patient.

The invention in claim 1 differs from the one in D1 in that the front piece of the garment is wholly or partly made up of an outer layer of a material with little air permeability and an inner layer of a material with a higher air permeability than the outer layer and in that at least one inlet that is connectable to a source of warm air is located on the front piece of the garment and leads to the space between the inner and outer layer.

D2 reveals a blanket for use with forced air convection systems. It is considered to cover a patient and allow for access to portions of a patient's body before, during and after surgery. The blanket (100) is made up of an upper sheet material (110) and of an inner sheet material, sealed together around respective peripheral edges to form a cavity there between. The inner sheet has a plurality of perforations or small exit holes formed there through which allow air to escape from the blanket (100) toward a patient. The inner sheet extends over at least a part of the outer sheet. The blanket (100) includes an inlet part (130), for attachment to a source of forced air, which will be used to inflate the blanket and to provide warming air to the patient through the perforations or holes in the inner sheet. Further in D2, the blanket comprises openable parts to allow access to the area for operation.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

The invention in claim 1 differs from the one in D2 in that it is a patient garment having sleeves and comprising a back piece.

D3 also discloses an inflatable air blanket. It is directed to regulate the body temperature of a treated patient, for example with a variety of surgical procedures. The blanket in D3 corresponds to the front piece in the characterising part of claim 1 and differs from the claimed invention in the same way as D2.

D4 discloses garment (10) for patients. The garment is used for maintaining body temperature at a desired degree of heating or cooling. The garment (10) discloses a front piece (11, 12) and back pieces (16, 17) and is directed to control the body temperature of a patient. The garment (10) is made of a lateral stretch fabric with small tubes attached to the garment for conveying heating or cooling fluids. The front and back pieces are detachably and reclosably connected to each other so as to provide easy donning or doffing of the garment and to provide selective access to different areas of the body. The connections are made up of mechanical connections, zippers. The invention in claim 1 differs from the one in D4 in the same way as the one in D1.

D5 reveals a heat conserving or cooling suit enclosure (10) of plastic sheet for a patient, for example, undergoing a surgical procedure. The body enclosure includes a head element (11), arm elements (12), thoracic/abdominal elements (14, 15) and leg elements (16, 17). The suit (10) is preferably made of a substantially impermeable plastic sheet. Heated or cooled gas or air is supplied to the suit (10) by closing a seam around an inlet tube or tubes (52).

The invention in claim 1 differs from the one in D5 in that the front piece is made up of two layers, between which a space is formed, in that the source of warm air leads to the space between the inner and outer layer and in that the inner layer has higher permeability than the outer layer. This difference solves the problem of achieving an even distribution of warm air over the body.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX V

The claimed patient garment discloses another type of control of the body temperature of a patient than the one in D1 and the one in D4 and it is used before, during and after surgery.

The front piece of the claimed patient garment and the blankets in D2 and D3 discloses the same way of warming a patient by letting warm air into a space formed by an inner and outer layer, where the inner layer has a plurality of perforations or small exit holes formed there through which allow air to escape from the space toward the skin of a patient. D2 and D3 disclose blankets. The claimed invention discloses a patient garment with sleeves comprising a back piece. Those features solve the problems of inadequate cover of the back of the arms and the body of the patient. Additionally, it seems that the patient garment in claim 1 provides a better and more even warming of the whole body as it comprises sleeves, a front and a back piece.

None of D1-D5 comprises all of the features defined in claim 1. There are no indications in the prior art that would lead a person skilled in the art to apply the features from the cited documents and thus arrive at the invention as defined in claim 1 and, therefore, the claimed invention is not considered obvious for a person skilled in the art.

Accordingly, the invention defined in claims 1-10 is novel and is considered to involve an inventive step. The invention is industrially applicable.

Claims

1. Patient garment having sleeves and comprising a front piece (1) and a back piece (2), **characterized in** that the front piece (1) is wholly or partially made up of an outer layer (3) of a material with little air permeability and an inner layer (4) of a material with a significantly higher air permeability than the outer layer, which extends over at least part of the outer layer (3) and is attached to the latter in such a way that a space is formed between the outer and inner layer, and that at least one inlet (8,9) connectable to a source of warm air is located on the front piece of the garment and leads to the space between the inner and outer layer.
2. Patient garment according to Claim 1, **characterized in** that the front and back pieces (1,2) are detachably and reclosably connected with each other, at least in the area from the shoulder parts to the end of the sleeve.
3. Patient garment according to Claim 1 or 2, **characterized in** that the front piece (1) includes openable parts to allow access to the area for operation.
4. Patient garment according to Claim 3, **characterized in** that the garment is designed as a coat, that the front piece (1) has a central slit (5) which extends from the bottom end of the coat to its breast part, and that those parts of the front piece which extend along the edges of the slit are connected with each other by means of a detachable and reclosable connection (6,7).
5. Patient garment according to Claim 3, **characterized in** that the garment is designed as a pyjama with a top part (17) and a trouser part (18), and that the front piece (19) of the top part is connected with the back piece by means of a detachable and reclosable connection (28), at least along the sides from the lower end of the top part to the breast part thereof.
6. Patient garment according to any of Claims 1-5, **characterized in** that the inner layer (4) of the back piece (2) and the front piece (1) is made of an air-permeable non-woven and the outer layer (3) of the front piece is made

of a non-air-permeable material, e.g. a plastic film or a laminate of plastic film and non-woven.

- 5 7. Patient garment according to any of Claims 1-6, **characterized in** that the inner layer (4) extends over the whole of the outer layer (3).
- 10 8. Patient garment according to any of Claims 3-7, **characterized in** that the inner layer (4) is laminated to the outer layer (3) within the marginal area of the openable parts of the front piece (1).
- 15 9. Patient garment according to any of Claims 2-8, **characterized in** that the detachable and reclosable connections (6,7 and 15,16) which connect parts of the garment with each other are made up of mechanical connections, preferably so-called velcro connections.
10. Patient garment according to any of Claims 4, 6-9, **characterized in** that the garment has an openable back.